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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,173	06/12/2000	Antonio Guama	1195-003	5454

7590

07/12/2002

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/12/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/593,173

Applicant(s)

GUARNA ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 18-28 is/are pending in the application.
- 4a) Of the above claim(s) 4-9 and 18-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 10, 27 and 28 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

The 102(b) rejection of claims 1, 10-12 are withdrawn in light of applicant's remarks and amendment at paper no. 12/C. The 112, second paragraph rejection of claims 11-12 are withdrawn in light of applicant's remarks and amendment at paper no. 12/C.

(old rejections)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 10 in part are rejected under 35 U.S.C. 112, first paragraph for reasons of record at paper no.10. The phrase "one or more N in a ring" connotes that a ring can potentially contain 5 nitrogen atoms. Pentazolyl rings and pentazines do not exist and are not enabled by the specification.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation

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needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the breadth of the claims, R1, R2, R3, R4, and R6 encompasses a much wider Markush grouping of radicals than those radicals tested which consist of hydrogen. 2) the nature of the invention is that these compounds are inhibitors of steroid 5 alpha reductases. 5) the level of predictability in the art was low since only two compounds, compounds 2, 3, 5, 6, 7, 9, 10-octahydro-(1H)-benzo[c]quinolin-3-one and 2, 3, 5, 6, 6a, 7, 8,9 -octahydro-(3H)-benzo[c]quinolin-3-one, were tested for their inhibitory activity on 5 alpha reductase enzyme, where the R1, R2, R3, R4, and R6 moieties are all hydrogen.

The compounds showed an inhibition of greater than 50 %. However, the level of predictability regarding inhibiting activity is low because only these two compounds were tested. No compounds containing 5 nitrogens in a ring, for example were tested, for their inhibition activity. 6) the amount of direction provided by the inventor is poor, because the applicant only conducts tests for two compounds where R1, R2, R3, R4, and R6 is equal to hydrogen. The applicant does not test the whole breadth of compounds encompassing all of the moieties that these particular radicals can be. 7) the applicant only provides working examples for two, compounds 2, 3, 5, 6, 7, 9, 10-octahydro-(1H)-benzo[c]quinolin-3-one and 2, 3, 5, 6, 6a, 7, 8,9 -octahydro-(3H)-benzo[c]quinolin-3-one.

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of

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the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record at paper no. 10.

A. In claim 1, page 2, lines 6-7, and all other occurrences throughout claims 1-2, the phrase "saturated or aromatic heterocycle containing one or more N atoms" is indefinite. There is no upper limit on the amount of N atoms that the heterocycle can contain.

(new rejections)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all of the diseases claimed, many of which are unrelated The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement.

The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

These various diseases require different mechanisms and antagonists. There is no reasonable assurance that such a diverse genus of compounds would possess diverse properties to treat this laundry list of diseases which different mechanisms and antagonists.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the breadth of the claims, R1, R2, R3, R4, and R6 encompasses a much wider Markush grouping of radicals than those radicals tested which consist of hydrogen. 2) the nature of the invention is that these compounds are

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inhibitors of steroid 5 alpha reductases. 5) the level of predictability in the art was low since only two compounds, compounds 2, 3, 5, 6, 7, 9, 10-octahydro-(1H)-benzo[c]quinolin-3-one and 2, 3, 5, 6, 6a, 7, 8,9 -octahydro-(3H)-benzo[c]quinolin-3-one, were tested for their inhibitory activity on 5 alpha reductase enzyme, where the R1, R2, R3, R4, and R6 moieties are all hydrogen. The effects of these compounds were not tested for their effects on the specific diseases claimed in claim 27.

The compounds showed an inhibition of greater than 50 %. However, the level of predictability regarding inhibiting activity is low because only these two compounds were tested. No compounds containing 5 nitrogens in a ring, for example were tested, for their inhibition activity. 6) the amount of direction provided by the inventor is poor, because the applicant only conducts tests for two compounds where R1, R2, R3, R4, and R6 is equal to hydrogen. The applicant does not test the whole breadth of compounds encompassing all of the moieties that these particular radicals can be. 7) the applicant only provides working examples for two, compounds 2, 3, 5, 6, 7, 9, 10-octahydro-(1H)-benzo[c]quinolin-3-one and 2, 3, 5, 6, 6a, 7, 8,9 -octahydro-(3H)-benzo[c]quinolin-3-one.

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 10, 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 28, line 2, page 2 of the amendment 12/C, the term "compounds" is indefinite. It is unclear as to whether or not the applicant is claiming a composition claim or a compound claim. If the applicant is claiming a compound claim, the phrase "A fully and partially reduced benzo (c) quinolizine compound of formula I" suggested.

B. In claim 1, line 2, page 2 of the amendment 9/B, and in claim 2, line 1, page 3 of the amendment 9/B, the term "compounds" is indefinite. It is unclear as to whether or not the applicant is claiming a composition claim or a compound claim. If the applicant is claiming a compound claim, the phrase "A fully and partially reduced benzo (c) quinolizine compound of formula I" suggested.

C. In claim 10, the phrase "Pharmaceutical composition" should read "A pharmaceutical composition".

Response to Applicant's Remarks

112, first paragraph rejection

The applicant asked the examiner to clarify what is meant when the examiner said that the rejection of claims 13 in part, 14 in part, and the 112, second paragraph rejections of claims 2 and 15 in part were withdrawn at paper no. 10. The claims were

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only examined in part as far as they read on the elected subject matter. So these claims were also withdrawn in part.

The applicant alleges that when terms (in this case, "one or more" that are used in a patent claim are construed, they are to be read as being directed to operable materials and components. The applicant also says that it is improper for the examiner to postulate structures that may exist, but would not be considered by one who is skilled in the art as being within the scope of the disclosed invention.

However, the examiner notes that the applicant can not claim something that does not exist.

The phrase "one or more N in a ring" connotes that a ring can potentially contain 5 nitrogen atoms. Pentazolyl rings and pentazines do not exist and are not enabled by the specification. The claims are so broad that more than routine experimentation would be required to place the invention in possession of the public. The burden is upon applicants, not the examiner to enable the invention. The examiner has provided scientific reasons and relied on the Foreman Factors of *In re Wands* and *Ex Parte Foreman* as to why this phrase is not enabled.

112, second paragraph rejection of claim 1

The applicant did not add any new remarks about the 112, second paragraph rejection of the phrase "saturated or unsaturated aromatic heterocycle containing one or more N atoms" other than what was discussed regarding the rejection of this phrase in the 112, first paragraph rejection.

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The examiner notes that this phrase is ambiguous and even claims pentazolyl rings and pentazines do not exist. The claims are so broad that more than routine experimentation would be required to place the invention in possession of the public.

2. Claim 3 in part is objected to because it is based on a rejected claim.
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson



July 11, 2002



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